

The Board raised the question of public use more than one year prior to October 4, 1985, the filing date of the ultimate parent application, United States Patent Application Serial Number 784,857. DPC first began the use of blocking agents in analog based assays for free hormones in 1982. The first product, which

was released on July 15, 1982, contained 0.5% salicylate at 1X concentration as a selective blocker for albumin in a Free T4 assay. Free T3 assay was released on February 4, 1983 and also contained sodium salicylate as the selective blocker for albumin. However, these products and all other products released prior to October 4, 1984 did not contain an antibody (ligand binder) that was of an affinity and at a concentration effective to avoid stripping of T₃ and T₄ off of endogenous proteins. Consequently, these products did not truly measure free hormone levels and did not come within the scope of the instant claims.

The general theory behind the use of blockers was orally presented at the Tenovous Workshop on Quality Control held in Cardiff, Wales, on September 4, 1984. This work was then released to the public on October 4, 1984 through a publication by DPC (ZE001-320A) and later was published in the Communications in Laboratory Medicine Volume 1, No. 3, page 97 1985 (July 1985).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the

application, any patent issuing thereon, or any patent to which
this verified statement is direct d.

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